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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/004,428 | 12/06/2001 | Philip Rodney Kwok | P 282771 | 9777 |
| 23117 | 7590 | 01/20/2004 | EXAMINER | |
| NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714 | | | LEWIS, AARON J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |
| DATE MAILED: 01/20/2004 | | | | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-----------------------------|-----------------|-----------------------|
| Offic Action Summary | Application No. | Applicant(s) |
| | 10/004,428 | KWOK ET AL. <i>01</i> |
| Examiner | Art Unit | |
| AARON J. LEWIS | 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
 - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10/01/2003 (AMENDMENT).

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 24-31 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 24-31 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15. 6) Other: _____

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 24,25,28,29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49-68,84-104 of U.S. Patent No. 6,634,358. Although the conflicting claims are not identical, they are not patentably distinct from each other because for the reasons set forth below.

As to claim 24, a nasal mask cushion to sealingly connect a mask to a wearer's face, the cushion comprising (see preamble of claim 84): a nasal bridge region, a cheek region and a lip region (line 3 of claim 84); a first membrane comprising a substantially triangularly-shaped frame of resilient material having a first molded inwardly curved rim of said first membrane (lines 4 and 5 of claim 84); and a second membrane of resilient material, said second membrane being thinner and more flexible than said first membrane, said second membrane having a second molded inwardly curved rim; said

second membrane curved rim spaced a distance from said first membrane curved rim, said distance greater than a thickness of the first molded inwardly curved rim, said distance measured when the mask is not in use, a portion of said second membrane curved rim forming a face contacting seal (lines 6-11 of claim 84).

The differences between claim 24 and claim 84 are additional limitations in application claim 24 including a more flexible second membrane. Each of claims 24 and 84 define the first and second membranes as resilient material, the second membrane being thinner than the first. It stands to reasons that a thinner membrane made of resilient material would be inherently more flexible than a thicker membrane of resilient material. Therefore, the recitation in claim 24 of the second membrane being more flexible than the first would be an inherent property of the second membrane as defined in claim 84. consequently, claim 24 is not patentably distinct from claim 84 because it is anticipated by claim 84. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

As to claim 25, a nasal mask for connection to a wearer's face comprising: a mask body for connection with a supply of breathable gas (see preamble of claim 49 of patent ('358)); and a nasal cushion secured to said mask body, the body and cushion forming a nose-receiving cavity (lines 3 and 4 of claim 49), said cushion including: a nasal bridge region, a cheek region and a lip region (line 5 of claim 49); a substantially triangularly-shaped first membrane of resilient material having a first molded inwardly curved rim to surround a wearer's nose (lines 6-8 of claim 49); and a second membrane also of resilient material, said second membrane being more flexible than said first membrane, said second membrane having a second molded inwardly curved rim, said

second molded rim being of the same general shape as said first molded rim and fixed to and extending away from said first membrane so as to have a second membrane inner surface spaced a distance from an outer surface of said first molded rim, said distance greater than a thickness of the first molded inwardly curved rim, said first distance measured when the mask is not in use, a portion of said second molded rim forming a face contacting seal (lines 9-14 of claim 49); wherein said seal portion is substantially coterminous with respect to said second molded rim and is resiliently deformable towards said first membrane in use of said mask.

The difference between claim 49 of patent ('358) and claim 25 of the instant application is the additional recitation in claim 49 of at least a portion of the second molded rim remaining spaced from the first molded rim when the mask is connected to the wearer's face (lines 16-18 of claim 49); consequently, claim 49 includes more limitations than claim 25. Thus the invention of claim 49 is in effect a "species" of the "generic" invention of claim 25. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

Claims 28 and 29 are substantially equivalent in scope to claims 24 and 25, respectively and are anticipated by claims 84 and 49 of patent ('358) for the reasons set forth above with respect to each of claims 24 and 25.

3. Claims 26 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 6,112,746. Although the conflicting claims are not identical, they are not patentably distinct from each other because for the reasons set forth below.

As to claim 26, a nasal CPAP treatment apparatus comprising (see preamble of claim 18): a flow generator for the supply of gas at a pressure elevated above atmospheric pressure (lines 2-3 of claim 18); a gas delivery conduit coupled to said flow generator; and a nasal mask in turn coupled to said conduit to said nasal mask (lines 4-6 of claim 18) including: a mask body for connection with a supply of breathable gas; and a nasal cushion secured to said mask body, the body and cushion forming a nose-receiving cavity (lines 7-10 of claim 18), the cushion including: a nasal bridge region, a cheek region and a lip region (line 12 of claim 18); a substantially triangularly shaped first membrane of resilient material having a first membrane having a first inwardly curved rim (lines 13-15 of claim 18); and a second membrane having a second molded inwardly curved rim also of resilient material, said second membrane being relatively more flexible than said first membrane, and being of the same general shape as said first molded inwardly curved rim and fixed to and extending away from said first membrane so as to have an inner surface spaced a distance from said first molded rim, said distance greater than a thickness of the first inwardly curved rim, said distance measured when the mask is not in use, a portion of said second molded rim forming a face contacting seal (lines 16-28 of claim 18); wherein said seal portion is generally coterminous with respect to said second molded rim and is resiliently deformable towards said first membrane in use of said mask (lines 30-33 of claim 18).

The differences between claim 18 of patent ('746) and claim 26 of the instant application include the recitations said second membrane inner surface spaced a second distance from said first molded rim, said second distance greater than said first

distance; consequently, claim 18 includes more elements and is thus more specific. Thus the invention of claim 18 is in effect a "species" of the "generic" invention of claim 26. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

Claim 30 is substantially equivalent in scope to claim 26 and is anticipated by claim 18 of patent ('746) for the reasons set forth above with respect to claim 26.

4. Claims 27 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,112,746. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth below.

As to claim 27, a nasal mask cushion for sealingly connecting a mask to a wearer's face (see preamble of patent claim 1), comprising: a substantially triangularly-shaped frame of resilient material having a first membrane, the first membrane including a first molded inwardly curved rim (lines 4-6 of claim 1); and a second membrane of resilient material, said second membrane being more flexible than said first membrane, said second membrane having a second molded inwardly curved rim, said second membrane curved rim spaced a distance from said first membrane curved rim, said distance greater than a thickness of the first molded inwardly curved rim, said distance measured when the mask is not in use, a portion of said second membrane curved rim forming a face contacting seal (lines 7-18 of claim 1).

The differences between claim 27 and claim 1 include recitations of said second membrane curved rim spaced a first distance from said first membrane curved rim in

said cheek region and said second membrane curved rim spaced a second distance from said first membrane curved rim in said nasal bridge region, said second distance greater than said first distance; consequently, claim 1 includes more elements and is thus more specific. Thus the invention of claim 1 is in effect a "species" of the "generic" invention of claim 27. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

Claim 31 is substantially equivalent in scope to claim 27 and is anticipated by claim 1 of patent ('746) for the reasons set forth above with respect to claim 27.

Response to Arguments

5. Applicant's arguments filed 10/01/2003 have been fully considered but they are not persuasive.

As to applicant's arguments regarding the lack of the first molded curved rim being inwardly curved, it is submitted that dependent claim 91 of patent ('358) recites that the first curved rim is inwardly curved.

As to applicant's arguments regarding the claimed distance between first and second inwardly curved rims being a distance which is greater than the thickness of the first molded inwardly curved rim, it is submitted that the distance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular distance. The distance arrived at would depend upon the desired degree of sealing against a wearer's face and depend upon the size of the mask.

As to applicant's arguments regarding the second membrane being relatively more flexible than the first membrane as recited in application claim 25, it is submitted that

dependent claim 56 recites the first membrane being thicker than the second membrane. Therefore, it stands to reason that the thinner second membrane would be relatively more flexible than the first.

As to applicant's arguments regarding the distance between the first and second membranes in claim 25, it is submitted that the distance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular distance. The distance arrived at would depend upon the desired degree of sealing against a wearer's face and depend upon the size of the mask.

As to applicant's arguments regarding claim 26 including the claimed distance between the first and second membranes, it is submitted that the distance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular distance. The distance arrived at would depend upon the desired degree of sealing against a wearer's face and depend upon the size of the mask.

As to applicant's arguments regarding claims 27 and 31 including the claimed second membrane being relatively more flexible than the first membrane and the distance between the first and second membranes, it is submitted that claims 8 and 9 define the thickness of each of the first membrane (i.e. 1.5mm) and the second membrane (0.35mm), the second membrane being thinner (and also being made from the same material as defined in claim 7) would impart more flexibility to the second membrane than the first; and as to the claimed distance between membranes, it is submitted that the distance can be arrived at through mere routine obvious

experimentation and observation with no criticality seen in any particular distance. The distance arrived at would depend upon the desired degree of sealing against a wearer's face and depend upon the size of the mask.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
January 11, 2004